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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,487	01/07/2002	Spiros Fotinos	224.0509-US	3570
20311	7590	08/09/2006	EXAMINER	
LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,487

Applicant(s)

FOTINOS ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/9/03, 11/20/03, 5/5/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of IDS, terminal disclaimer, amendment and remarks, all filed 5/5/06; associate power of attorney filed 4/27/06. Claims 24 to 45 are pending.

Information Disclosure Statement

Previously considered form 1449 and examiner's 892 for application serial number 09/340,338 are filed as current IDS. It is requested that applicant provide/file the IDS on appropriate form 1449 for examiner's consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 24-34, 36-40 and 43-45 remain rejected under 35 U.S.C. 102(e) as being anticipated by Biederman et al. (US 5,980,921).

Biederman discloses topical composition comprising effective amount of active agent in a more preferred amount of about 0.1% to about 10% and cosmetically acceptable topical carrier

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such as propylene glycol and polyethylene glycol (column 2, lines 42-46; column 3, lines 19-21; column 4, lines 38-43; column 5, lines 4-16). The composition of Biederman is formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses; the composition comprises surfactants such as sodium lauryl sulfate in a preferred amount of from about 5% to about 10% (column 6, lines 17-28 and 39-46); the composition comprises film forming polymer that is not tacky (column 8, lines 56-67). Polyvinylpyrrolidone, one of the preferred polymers is present in amounts of 0.5 wt% to 10 wt% (column 9, lines 37, 43); wherein the composition further comprises plasticizers such as glycols and glycerol in amounts of about 0.5% to 30% (column 10, lines 12-38). It is specifically disclosed that the preferred polymer and the plasticizing solvent (plasticizer) are chosen such that the polymer and the plasticizing solvent are in the aqueous phase of the emulsion which reduces tacky sensation of the polymer on the users hands during application (column 10, lines 39-46). Niacinamide, pyridoxine, panthenol, pantothenic and mixtures thereof are the primary actives (column 4, lines 21-28). In addition to the primary actives, the composition of Biederman optionally contains other active agents namely: anti-inflammatory agents, retinoids, antimicrobial agents, antiandrogens, sunscreens, sunblocks, anti-oxidants/radical scavengers, chelators, hydroxyl acid anti acne agents such as salicylic acid and lactic acid, desquamation agents, depilation agents and skin lightening agents (columns 11-16). The glycols meet the limitations of claim 30. Polyvinylpyrrolidone meets the limitation of claims 31-34. Antimicrobials meet the limitations of claim 29. Lauryl sulfate meets the limitation of claim 36. Propylene glycol and lauryl sulfate meet the limitation of permeation enhancer. As a cleansing product, the composition of Biederman meets the limitations of claims 43-45.

The comprising language of the claims is open and does not exclude other components present in the composition of Biederman and thus meets the limitations of the claims.

Response to Arguments

3. Applicant's arguments filed 5/5/06 have been fully considered but they are not persuasive.

It is noted that Biedermann discloses a formulation comprising **film-forming polymer** that is not tacky (column 8, lines 56-67) with polyvinylpyrrolidone as one of the preferred polymer and present in amounts of 0.5 wt% to 10-wt% (column 9, lines 37 and 43). The water-dissolvable filmogenic polymer of the instant claim is polyvinylpyrrolidone or chitin or chitosan or xanthan gum or karaya gum or zein or hordein of gliadin or combinations thereof (instant claim 31). Thus, polyvinylpyrrolidone of the Biedermann formulation meets the limitation of the filmogenic polymer of claim 24 and then 31.

The physical form of the Biedermann cleansing formulation is "***toilet bars***, liquids, shampoos, bath gels, hair conditioners, hair tonics, ***pastes***, or mousses. ***Toilet bars*** are most preferred since this is the form of cleansing agent most commonly used to wash the skin," (column 6, lines 41-44).

A. Regarding applicant's argument that Biedermann's formulation is not a device but an emulsion, it is noted that an emulsion is also a delivery device since the emulsion is capable of delivering active agents such as niacinamide or mixture of niacinamide and one more optional active agents (column 4, lines 30-37; column 11, line 12; column 12, lines 30, 48, 62; see also columns 13 and 14 for other optional active agents).

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B. Regarding applicant's argument that Biedermann's formulation is not a dry uniform layer, it is noted that one of the physical forms of Biedermann's formulation is a toilet bar (column 6, line 41) and a toilet bar which is used as a cleansing agent is dry and of uniform layer such that applicant's claim to a broad water-dissolvable, non-tacky and dry uniform layer reads on Biedermann's toilet bar. In this wise, applicant's reference to column 8, lines 56-67 is noted and in this except Biedermann discloses the presence of a film-forming polymer in the composition in an emulsion and specifically discloses that the film when formed must be removable by water and that the polymer must not be tacky (column 8, lines 56, 63-67). Furthermore, Biedermann discloses a toilet bar, which is dry and not tacky and of uniform layer. The toilet bar, one of the physical forms of the Biedermann's formulation contains the polyvinylpyrrolidone film-forming polymer (column 9, lines 43 and 48) meeting the limitation of the formulation of instant claim 24.

C. Regarding applicant's argument that Biedermann does not describe a film that is "dissolvable upon application" and a device that is suitable for application to the skin, it is noted that while the recitation of applicable to the skin in claim 24 is an intended use of the delivery device, Biedermann specifically discloses that toilet bars are most preferred form of cleansing agents that is most commonly used to wash the skin (column 6, lines 42-44). Secondly, one of the water-dissolvable filmogenic polymer of the claims is polyvinylpyrrolidone and the polyvinylpyrrolidone of Biedermann must also be water-dissolvable because a product and its properties cannot be separated. Thirdly, while layer may be a film, the claim 24 does not recite a film. Applicant in the remarks however, admits that Biedermann's formulation is capable of forming a film.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 35 and 42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Biederman et al. (US 5,980,921).

Biederman is discussed above and discloses the film forming composition of the claimed invention. Biederman does not disclose a single layer device. Regarding claim 35, there is no demonstration that at least 75% of the film-forming polymer provides unusual/unexpected results to the composition. The cleansing formulation is applied to the skin and the application may be in a single layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the composition of Biederman to the skin as a cleansing composition. One having ordinary skill in the art would have been motivated to apply the composition to the skin in a single layer with the expectation of uniform/efficient cleaning.

Response to Arguments

6. Applicant's arguments filed 5/5/06 have been fully considered but they are not persuasive.

D. Applicant argues: i) Biedermann is not an anticipatory art and examiner's failure to reject claim 24 under 35 USC 103 is concession that claim 24 is free of the art of

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record. ii) Furthermore, applicant states that the law is clear that “if an dependent claim is free of the art or record, then all claims depending from the independent claim are also free of the record.” iii) Also the examiner is not free “to point to some specific element of a dependent claim and burden applicants with a requirement to show unexpected result.” iv) That examiner failed to show that the “missing” element in Biedermann, which is “the dryness of the claimed device” is provided by another reference and that if examiner is basing the rejection on personal knowledge, the examiner is required to make such knowledge of record with a declaration under 37 CFR 1.132.

Regarding D i), it is noted that claim 24 was rejected as being anticipated by Biedermann according to the rejection and response to applicant’s argument above.

Regarding D ii), it is noted that claim 24 is not free of the art of record and reference is thus made to the above rejection under 35 USC 102 and the response to applicant’s argument.

Regarding D iii), it is noted that it is proper to reject a dependent claim under 35 USC 103 if the independent claim from which the dependent claim comes from is rejected under 35 USC 102. The dependent claim contains within it the limitations of the independent claim so that when a dependent claim has limitations that are not anticipated by the prior art and the independent claim is anticipated by the prior art (of record say), the relevant question is whether, the limitation in the dependent claim would have been obvious over the prior art at the time the invention was made and the standard for 35 USC 103 is set forth in MPEP in at least nos. 2141 [R-3], 2143.03 and 2144.

Regarding D iv), it is noted that, a toilet bar (see Biedermann at column 6, lines 41 and 42) is a dry uniform layer that is not tacky as described in the response to applicant’s remarks.

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Thus, examiner has not relied on a personal knowledge and a declaration by the examiner under 37 CFR 1.132 is not required.

“When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

It is further noted that although Biedermann does not specifically disclose a single layer as claimed in claim 42, a toilet bar, may be considered to be inherently a single layer and in the alternate it would be prima facie obvious to the artisan that a toilet bar would be a single layer.

Double Patenting

The provisional rejection of claims 24, 25, 30-32 and 35 the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67 and 71-75 of copending Application No. 09/340,338 is withdrawn because the filing of terminal disclaimer overcomes the rejection.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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